

## REMARKS

Applicant would like to thank Examiner Clow for the indication in the office action of May 18, 2004, that the claims are allowable over prior art previously of record. A number of minor rejections based on wording of the claims are pending. All claims have been amended along the lines suggested by the examiner to expedite prosecution, where appropriate.

In this regard, it should be noted that the new amendment procedure at the USPTO that came into effect in July of 2003 appears to favor amendment of claims by use of underlining to indicate added matter even in cases where underlining already exists in claims (e.g., in a mathematical formula). While such an amendment scheme *might* be easier to follow in some circumstances (in terms of indicating exactly what changes have been made), it has been the experience of the undersigned that added underlining in a claim already containing underlining can lead to confusion at the Patent Office as to what is intended. Accordingly, claims already containing intended "underlining" have instead been amended by replacing those claims with new claims, even though the amendments were minor. A chart showing correlation of old and new claims is included below for the convenience of the examiner.

<u>Old Claim Number</u>	<u>Replacement Claim</u>	<u>Comment</u>
1	87	Claim 1 contained formulas
—	88	New dependent claim
13	89	Claim 13 contained a formula
15	90	Claim 15 contained a formula
19	91	Claim 19 contained formulas
20	92	Claim 20 contained formulas
22	93	Claim 22 contained a formula

Regarding new claim 88, since claim 1 (now claim 87) was amended to clarify how activity hours are initially calculated (at the request of the examiner), claim 88 was added as a dependent claim to clarify that the added language of claim 87 does not

require that the calculations occur *during* practice of the method.<sup>1</sup> Instead, dependent claim 88 specifies that the calculations could have occurred previously and that data can later be looked up by the user as part of the method. This claim is supported by language on page 15 of the original specification in the paragraph immediately following Equation I.

Turning now to the specific objections and rejections, claims 19 and 84 were rejected under 35 USC 101 as being directed to non-statutory subject matter. Applicant understands that this occurred because of the lack of clarity in the wording of the claims, since claim 84 was said to “recite an intended product” (although still rejected under 35 USC 112, 2<sup>nd</sup> paragraph). Claims 19 and 84 have been combined into new claim 91, and the wording has been clarified to more clearly indicate a product-by-process claim, as was originally intended. As is known, a product-by-process claim that defines the claimed product in terms of the process by which it is made is proper under section 101. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). [MPEP 8<sup>th</sup> Ed., sect. 2173.05(p)]

A number of claim issues were raised under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs. Each of these is addressed in turn below.

In claim 1 (now claim 87) and other claims that did not contain an indication that the method or product-by-process composition was directed to use of “an <sup>131</sup>I-labeled anti-B1 antibody radiopharmaceutical,” this language has been added to the claims (directly or by dependency), as suggested by the examiner.

Claim 1 (now claim 87) and other claims have also been amended to clarify how activity hours can be obtained, as suggested by the examiner. The added language was previously present in claim 20 (not objected to on this point), although minor modifications to that language were made for clarity and to make the added language fit the syntax of the new claims.

Claim 4, which referred to “maximum effective mass [being] correlated to lean body mass,” has been canceled. Claim 85 (not objected to) addresses this issue and uses clearer language to specify a correlation method.

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<sup>1</sup> This is true of other calculations and of other steps as well, which can be conducted at different times and places and by different doctors, technicians, etc., in the process of determining the desired dosage for a

Claim 9, referring to “exponential terms” in a somewhat vague manner, has been canceled. Other dependent claims describe similar subject matter in clearer terms (e.g., claim 24).

Claim 10, which previously referred to “determining 37% injected activity” has been clarified as suggested by the examiner.

Claim 13, now claim 89, has been amended along the lines suggested by the examiner to indicate that “solving” of the equation is for “residence time.”

Claim 20 (now claim 92) previously used the language “the sum of electron energy and photon energy” in referring to part of Equation I. Clarification of how this sum was obtained was requested by the examiner.

As stated in the specification, the necessary data that is to be summed (surely there is no difficulty with the process of taking a sum) was already available in the scientific literature, including published pamphlets: “for each radionuclide, using the equation above *along with published data, such as that obtained from MIRD pamphlets*, one can generate tables or create databases that are dependent on the radionuclide and the patient, and which will provide an indication of the activity hours needed to deliver a desired total body dose to the patient” (specification, page 15, immediately following Equation I; emphasis by italics added). MIRD stands for “medical internal radiation decay,” and medical internal radiation decay data is the data that is summed in this calculation. Today, in addition to being provided in pamphlets, MIRD data is readily available on the internet and can be checked by the examiner. See, for example, the following government-sponsored URL: <http://www.nndc.bnl.gov/mird/>. This is a search page that provides access to medical data for any radionuclide and is maintained by the National Nuclear Data Center (the NNDC) at Brookhaven National Laboratory. When “131I” (to represent the radionuclide <sup>131</sup>I) was inserted in this search site by the undersigned, data having an effective date of 1994 was displayed, indicating the data was known and publicly available prior to this invention (provisional application filing date: 1998) and thus available for the indicated action (i.e., obtaining “the sum of electron energy and photon energy”). No amendment of the claim is necessary.

Clarification was also requested for the symbol “ $\Phi^{TB}$ .” This symbol represents the total body (“<sup>TB</sup>”) energy absorbed for any one photon (typically a gamma ray)

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given patient.

produced by radioactive decay. “ $\Phi$ ” is the Greek symbol “phi,” equivalent to the English “P” (for “photon”). All of the individual total-body photon energy values (gamma ray energies) for decay events of a particular radionuclide are summed to produce the amount of the photon energy absorbed by the body. The resulting value is added to the electron energy resulting from beta decays (the left portion of the bracketed terms in this formula) to give the total radiation energy absorbed by the body. The meaning of  $\Phi^{TB}$  will be self-evident to one skilled in the art of the invention who saw this formula in the context of the specification or claims, so that amendment of the claim is not necessary.

Another objection to claim 20 involved the language “to obtain a value” (the objection being that it was not clear what the value represented). Applicant continues to believe that the meaning of “value” in the original language could be understood in context. However, language has been added to replacement claim 92 to indicate that the intended value represents the therapeutic dose, as correctly suggested by the examiner. Since the initial value obtained in the calculation, however, can optionally be modified by a further calculation as stated in the claim, the phrase “initial therapeutic dose” has been used to describe the results of the initial calculation to avoid any confusion by use of “therapeutic dose” (without modification) in two locations. Keep in mind, however, that this initial calculated value might be the final calculated value for the therapeutic dose if the optional adjustment of the dose (the final, optional step of the claim) is omitted.

Two objections existed regarding claim 22 (now claim 93). Clarification was requested regarding the meaning of the phrase “number of exponential terms.” As pointed out in the specification, clearance of various radioisotopes from the body is best described in some case by equations containing different numbers of exponential terms (see specification, page 10, first two paragraphs of section entitled “Clearance Profile”). A triexponential equation would, for example, have three exponential components, so in this case,  $n = 3$ . Amendment of the claim is needed in order for this point to be understood.

As for the second objection to claim 22, regarding “intercepts and slopes,” language from the specification has been added to clarify the meaning of these terms and how they could be handled. For basis of the added language, see page 23, discussion of Equation IV.

Although not objected to in claim 15, the same language that resulted in rejection of claim 22 was also present in claim 15. Accordingly, the same changes discussed above regarding claim 22 (now claim 93) were made in claim 15 (now claim 90).

The limitations of claim 84 has been combined into claim 19 (now claim 91) and claim 84 has been canceled. The wording of new claim 91 is discussed above in the section discussing 35 USC 101 rejections.

Claim 85 has been amended as suggested to change "patient would belong" to "patient belongs," as suggested by the examiner. However, applicant would like to make clear for the record that a statement saying that a patient "belongs" to a patient population does not indicate that the group of individuals who were tested to determine characteristics of the patient population includes the specific patient being treated now. Instead, "belongs" means that the patient has the characteristics of the "patient population" for the purpose of medical treatment.

#### **Conclusion and Conditional Request for Interview**

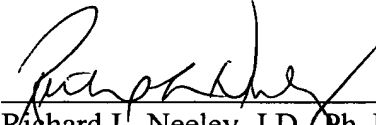
If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 843-5070. **The undersigned believes that an interview would be helpful if the Examiner finds that the current wording is not sufficiently clear, and such an interview (by telephone) prior to the issuance of any further office action other than an allowance is requested.**

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